REMARKS

The present application is a continuation-in-part of PCT/JP01/10234 filed November 22, 2001. Claims 1-19 were presented at the time of filing. In response to a Restriction Requirement dated November 1, 2005, Applicant elected the claims of Group I (claims 1-3 and 15-19); claim 15 was cancelled and rewritten as new claim 20. Claims 1-14 and 16-20 were, therefore, pending in the application with claims 4-14, 18 and 19 withdrawn from consideration as being directed to non-elected inventions. Claim 2 was cancelled in response to a non-final Office Action. Claims 4-16 and 18-20 are cancelled above; claims 1, 3 and 17, therefore, remain pending in the application.

Claim Objection

Claims 1 is amended above in accordance with the Examiner's suggestion.

Rejection Under 35 U.S.C. § 101

Claim 16 is cancelled above rendering the rejection under 35 U.S.C. § 101 moot.

Rejection Under 35 U.S.C. § 112, first paragraph

Without acceding to the accuracy of the rejection, claims 16 and 20 are cancelled above rendering the written description and scope of enablement rejections of those claims under 35 U.S.C. § 112, first paragraph moot.

Rejection under 35 U.S.C. § 102

Claim 16 is cancelled above rendering the rejection of that claim under 35 U.S.C. § 102 moot.

Claims 1, 3 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ohnishi et al. (22nd Annual Meeting of the Molecular Biology Society of Japan) Program and Abstracts, December 7-10, 1999. According to the Office Action (as stated in the previous Office Action), Ohnishi et al. teaches the immunoprecipitation of a polypeptide referred to as "LICK" from a HeLa cell extract. The abstract further discloses that the polypeptide is about 400 or 430 KDa, has kinase activity and has an internal sequence (approximately 25 amino acids in length) that is 100% identical to amino acids 2331 to 2356 of SEQ ID NO: 2 (3629 amino acids). The Office Action concludes that the instant claims are anticipated by the teaching of Ohnishi et al. and that a polypeptide obtained in accordance with the teachings of the abstract would inherently possess SMG-1 activity, thereby meeting that limitation of the present claims. Applicants respectfully disagree.

As a preliminary matter, Applicants urge that the oral presentation by Dr. Ohnishi, does not constitute a "printed publication" in view of *In re Klopfenstein*, 380 F.3d 1345 CAFC 2004. With regard to scientific presentations, the court in Klopfenstein held "...it is important to note than an entirely oral presentation at a scientific conference that includes neither slides nor copies of the presentation is without question not a "printed publication" for the purposes of 35 U.S.C. §102(b). Furthermore, a presentation that includes a transient display of slides is likewise not necessarily a "printed publication." *See, e.g.,* Regents of the Univ. of Cal. v. Howmedica, Inc., 530 F.Supp. 846, 860 (D.N.J.1981) (holding that "the projection of slides at the lecture [that] was limited in duration and could not disclose the invention to the extent necessary to enable a person of ordinary skill in the art to make or use the invention" was not a "printed publication"), *aff'd,* 676 F.2d 687 (3d Cir.1982) (unpublished table decision). *Howmedica*...stands for the

important proposition that the mere presentation of slides accompanying an oral presentation at a professional conference is not per se a "printed publication" for the purposes of §102(b). Thus, Applicants maintain that the slide presentation of Dr. Ohnishi was a transient display and therefore, does not constitute a "printed publication" for the purposes of §102(b).

Furthermore, it is well settled that to serve as an anticipating reference, the cited reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). See Bristol-Myers Squibb v. Ben Venue Laboratories, Inc., 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."). In the present case, neither the abstract nor the slide presentation by Dr. Ohnishi at the 22nd Annual Meeting, on its face, teaches the claimed polypeptide, i.e., an isolated polypeptide comprising amino acids 129 to 3657 of SEQ ID NO.: 2.

As stated in the abstract, Ohnishi et al. "identified a human cDNA encoding a novel [member of the] PIKK family." and "In immunoprecipitates derived from HeLa cells, we confirmed that both p400/430 exhibited an autophosphorylation activity..." The abstract further states that "Western blotting was carried out using plural specific antibodies *prepared in accordance with the sequence deduced from the cDNA...*"

The structure of the hSMG-1 cDNA, however, was not disclosed. Moreover, with the exception of a short stretch (25) of amino acids of the PIKK domain that are highly homologous to several other polypeptides, the sequence of the predicted translational product of the human SMG-1 cDNA was also not disclosed until the following year, at the 23rd Annual Meeting of the Molecular Biology Society of Japan. Thus, no structural information, either the nucleotide

sequence of the cDNA or the amino acid sequence of the polypeptide was available from which one of skill in the art could generate an isolated hSMG-1 polypeptide and subsequently, raise an antibody specific for hSMG-1, so that the antibody could be used to isolate the claimed polypeptide by immunoprecipitation of a cell extract.

The Office Action appears to suggest that the claimed polypeptide is anticipated by a method of obtaining the claimed protein based on the disclosure of a 25 amino acid region of the claimed protein. In the oral presentation, Ohnishi disclosed a 25 amino acid region (corresponding to amino acids 2331 to 2356) of the 3654-amino acid human SMG-1 protein having homology to several other proteins of the PIK-related protein kinase family. Ohnishi, however, provided no information regarding the conformational location of this region. So, while in theory, one could generate an anti-peptide antibody to any epitope within the 25 amino acid region, without further structural information regarding the conformational location of the epitope within the protein (for example, its accessability to the cognate antibody), one could not conclude that an antibody generated to an epitope within the 25 amino acid region would be able to bind to the epitope(s) on a properly folded protein. Thus, while it may be possible to produce an anti-peptide antibody, its specificity for and ability to immunoprecipitate the claimed protein does not necessarily follow.

Thus, the assumption that one could generate an antibody directed to an epitope within the 25 amino acid region disclosed in Ohnishi's presentation and use that antibody to immunoprecipitate Applicants' claimed protein does not, in Applicants view, represent a predictable solution to the problem of isolating the claimed protein in the absence of further information regarding the protein's conformation.

Thus, the disclosure in the abstract from the 22nd Annual Meeting abstract of various characteristics of the claimed polypeptide, does not teach or suggest either the claimed invention or a method for obtaining it. The Ohnishi reference, therefore, does not anticipate the claimed invention. Withdrawal of the rejection under 35 U.S.C. §102 in view of Ohnishi et al. is respectfully requested.

It is respectfully submitted that the above-identified application is now in a condition for allowance and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

Kathy Smith Dias
Attorney for Applicants
Reg. No. 41,707

Dated: October 29, 2007

Address for Correspondence:
Kathy Smith Dias
HESLIN ROTHENBERG FARLEY & MESITI P.C.
5 Columbia Circle
Albany, New York 12203-5160
Telephone: (518) 452-5600
Facsimile: (518) 452-5579

N:\USERS\2352 Morita&Assoc\2352002\TO PTO\2352002-PR01-RRR.doc